Suggested Format for Residue Chemistry Study Reports

Nature of the Residues in Plants OPPTS 860.1300

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

Residue Chemistry Study R	eports – NATURE OF THE RESIDUES IN PLANTS
Instructions to create PDF	Document Format
Create Bookmarks for each item in document format column.	 Study Title Page. Statement of Data Confidentiality No confidentiality claims can be made for electronically submitted studies at this time. GLP Statement. QA Statement. Table of Contents.
Create links in summary to related text and tables in body of study report or appendices	Executive Summary. Summary of Background Information & Experimental Design. Summary of Results
Create links to related tables	 Background Information and Experimental Design. Background Information – See Tables 1 and 2. Experimental Design – See Tables 3 - 6. Analytical Methodology. Results and Discussion – See Tables 7 - 11

TABLE FORMATS

Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Table 1 – Test Compound Nomenclature.

Compound	Chemical Structure
Common Name.	
Company experimental name.	
IUPAC name.	
CAS name.	
CAS#	
End-use product/EP.	

Table 2 – Physicochemical Properties.

Parameter	Value	Reference
Melting point/range		
рН		
Density		
Water solubility (°C)		
Solvent solubility (mg/L at°C)		
Vapor pressure at°C		
Dissociation constant (pKa)		
Octanol/water partition coefficient Log (Kow)		
UV/visible absorption spectrum		

Table 3 – Test Site Information.

	Soil Characteristics				Environm Conditio	
Testing Environment*	Type	% OM	pН	CEC	Temperature	Rainfall

^{*}outdoor test plots, greenhouse, plant growth chambers, etc.

Table 4 – Crop Information.

Crop/Crop group	Variety	Growth stage at application	Growth stage at harvest	Harvested RAC	Harvesting procedure

Table 5 – Test Material Characteristics.

Chemical structure	[Insert structure]	[Insert structure]
Radiolabel position		
Lot No.		
Specific activity (Bq)		
Code		

Table 6 – Use Pattern Information.

Chemical name.	
Application method.	
Application rate.	
Number of applications.	
Timing of applications.	
РНІ	

Table 7 – Summary of Storage Conditions.

Matrix (RAC or Extract)	Storage temp. (°C)	Actual study duration (days or months)	Limit of demonstrated storage stability (days or months)

Table 8 – Total Radioactive Residues (TRRs) in [matrices].

	Timing and	PHI	Aa-l	abel	Bb-l	abel
Matrix	application no.	(days)	% TRR	ppm	% TRR	ppm

Table 9 – Distribution of the Parent and the Metabolites in Plant Matrices when Dosed with ¹⁴C-labeled Test Compound X [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme, matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental design.].

	Matrix 1		Mat	rix 2	Mat	rix 3
	(TRR =	xx ppm)	(TRR = xx ppm)		(TRR = xx ppm)	
Metabolite Fraction	% TRR	ppm	% TRR	ppm	% TRR	ppm
Surface wash						
[Add a row for each identified compound]						
[Unidentified compound]						
Organosoluble						
[Add row for each identified compound]						
[Unidentified compound]						
Aqueous soluble						
[Add row for each identified compound]						
[Unidentified compound]						
Total extractable (Aqueous + organic)						
Total identified						
Total unidentified						
Total bound residues (PES)						
% Accountability Total (ppm)/TRR (ppm)* 100						

US EPA, Office of Pesticide Programs, Electronic Submission and Review October 21, 2002 **Table 10 – Summary of Characterization and Identification of Radioactive Residues in Plant Matrices Following Application of Radiolabeled** [chemical] at [rate] [Note: Modify the table and/or add tables as needed to accommodate the fractionation scheme,

matrices analyzed, radiolabel positions, sample timing, and other aspects of the experimental

design.]

uesign.j	Matrix 1		Matrix 2		Matrix 3	
Compound	% TRR	ppm	% TRR	ppm	% TRR	ppm
[Parent]						
[Metabolite 1]						
[Metabolite 2]						
[Metabolite 3]						
[Metabolite 4]						
Total identified.						
Total characterized.						
Total extractable.						
Total bound.						

Table 11 – Identification of Compounds from Metabolism Study.

Common name/code	Chemical name	Chemical structure